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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,307	10/14/2003	Martin Bluggel	B0004/7115	9843

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EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	**PAPER NUMBER**
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,307	BLUGGEL ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/04, 6/30/04, 11/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a method for separating a biosubstance mixture, classified in class 436, subclass 178.

II. Claims 13-16, drawn to a microtitration apparatus, classified in class 422, subclass 942.

III. Claim 17, drawn to a pipette tip, classified in class 422, subclass 100.

Inventions (I and II) and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Invention III cannot be used to perform the method of Invention I, and it cannot be used to make or use Invention II. Invention III has a design, mode of operation and effects that are different from those of Inventions I and II.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method does not require a microtitration apparatus with a foil .

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Paul Kudirka on June 22, 2007, a provisional election was made with the preservation of traverse to prosecute the invention of group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 12 objected to because of the following informalities:

"a pipetting robot" should be changed to "the pipetting robot" because proper antecedent basis for the term has been established in claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **1-12** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites that the method comprises multidimensional separation. The claim recites how the first dimension of separation is achieved (i.e. either fractionating binding or fractionating dissolution). However, the claim does not specify how the subsequent dimensional separations are achieved to produce sub-fractions. The claim vaguely recites that "two or more separation generations with different separating dimensions are used to successively separate the respective fractions into multiple discrete sub-fractions".

Because the steps involved in producing the sub-fractions are indefinite, for examination purposes, only the step of producing fractions will be considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim **8** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the step of performing an enzymatic digestion before the mass spectrometric analysis. However, the claims do not recite when the spectrometric analysis is performed. Therefore, the timing of the enzymatic digestion relative to the other steps is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **1-3, 11 and 12** are rejected under 35 U.S.C. 102(e) as being anticipated by Schneider et al. (US 6,537,432 B1).

Schneider et al. disclose a method for conducting multidimensional separation of proteins. The first dimension of separation is achieved by means of affinity chromatography (see lines 5-15, col. 26).

With respect to claims 11 and 12, the claims do not further limit claim 1 and therefore, the claims do not have patentable significance. Neither claim 1, 11 nor 12 positively recite the performance of a procedural step or a preparation step. Because the claims do not positively recite these steps, the means by which these steps are conducted do not have patentable significance.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1-4, 11 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by Hammen (US 5,240,602).

Hammen discloses a method for separating at least one substance, such as protein, from a mixture of substances (see lines 12-40, col. 6). The method comprises the step of providing affinity ligands inside of the wells of a microtiter plate, incubating the sample mixture with the ligands, and washing the ligands to remove the unbound species.

With respect to claims 11 and 12, the claims do not further limit claim 1 and therefore, the claims do not have patentable significance. Neither claim 1, 11 nor 12 positively recite the performance of a procedural step or a preparation step. Because the claims do not positively recite these steps, the means by which these steps are conducted do not have patentable significance.

Claims **1-3, 7, 11 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by Dorval et al. (US 5,561,045).

Dorval et al. disclose a method for separating a species from a mixture of species (see lines 1-15, col. 9). In this method, immunoglobulin is immobilized to hydrophobic regions of a flat substrate. The immunoglobulin is reacted with a sample

mixture to bind the species of interest, and the substrate is washed to remove the unbound species.

With respect to claims 11 and 12, the claims do not further limit claim 1 and therefore, the claims do not have patentable significance. Neither claim 1, 11 nor 12 positively recite the performance of a procedural step or a preparation step. Because the claims do not positively recite these steps, the means by which these steps are conducted do not have patentable significance.

Claims **1, 2, 8, 11 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by Nordhoff et al. (US 2002/0045204 A1).

Nordhoff et al. disclose a method for performing multidimensional separation of a protein mixture and the analysis of the separated proteins via mass spectrometry. The reference discloses that is preferable to perform an enzymatic digestion of the proteins prior to the analysis via mass spectrometry (see [0003]).

With respect to claims 11 and 12, the claims do not further limit claim 1 and therefore, the claims do not have patentable significance. Neither claim 1, 11 nor 12 positively recite the performance of a procedural step or a preparation step. Because the claims do not positively recite these steps, the means by which these steps are conducted do not have patentable significance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **9 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. in view of Cortes et al. (US 5,240,604).

Schneider et al. do not disclose size exclusion chromatography.

Cortes et al. disclose a multidimensional chromatographic system wherein the first dimensional separation is achieved by means of size-exclusion chromatography

conducted in a micro column (see lines 39-65, col. 3). Using this method, the sample can be first separated according to size.

In light of the disclosure of Cortes et al., it would have been obvious to separate proteins using size-exclusion chromatography prior to separating the proteins using the method disclosed by Schneider et al. to separate the protein mixture according to size.

Claims **5 and 6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammen in view of Wainwright et al. (US 5,876,918).

Hammen does not disclose the use of magnetic spheres.

Wainwright et al. disclose that the use of functionalized magnetic microspheres to extract or separate a species of interest, such as DNA, from a sample mixture is well known in the art (see lines 35-50, col. 1).

In light of the disclosure of Wainwright et al., it would have been obvious to one of ordinary skill in the art to use functionalized magnetic microspheres instead of the affinity ligands in the method disclosed by Hammel. The magnetic properties of the microspheres would facilitate collection of the isolated species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
6/22/07

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